K073259
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Toshiba America Medical Systems, Inc.
510(k) Pre-market Notification; XIDF-100A/B1 Image Processor

510(k) Summary

Date:	November 1, 2007
Submitter's Name:	Toshiba America Medical Systems, Inc.
Submitter's Address:	P.O. Box 2068, 2441 Michelle Drive, Tustin, CA 92781-2068
Submitter's Contact:	Paul Biggins, Director Regulatory Affairs (714)730-5000
Establishment Registration Number:	2020563
Device Proprietary Name:	XIDF-100A/B1, Image Processor
Common Name:	System, Image Processor, Radiology [Fed. Reg. No. 892.2050, Pro. Code: 90LLZ]
Regulatory Class:	II (per 21 CFR 892.2050)
Performance Standard:	None
Predicate Device(s):	Toshiba XIDF-100A (K002424) Siemens DynaCT (K042646)
Reason For Submission	Modification of existing device

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Description of this Device:
The XIDF-100A/B1 is an image processor that, when used in conjunction with the Toshiba Infinix Angiography System and a 3D Workstation, can acquire 2D images and convert them to 3D images. The system then transmits the 3D images to the 3D Workstation for display and viewing.

Summary of Intended Uses:
This device is intended to acquire 2D rotational images and convert them to 3D images.

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Technological Characteristics:
This device employs similar materials and processes as found in the predicate devices. The device is a PC based system that has software which is used for image acquisition and transmission.

Safety and Effectiveness Concerns:
This device is designed and manufactured under the Quality System Regulations as outlined in 21 CFR § 820. This device is in conformance with the applicable parts of the IEC 60601-1 {applicable portions}; IEC 60950-1.

Substantial Equivalence:
The XIDF-100A/B1 has similar functions and indications as those of the predicate devices:

Toshiba XIDF-100A; k002424
Siemens DynaCT; k042646

Therefore this device is substantially equivalent to devices that are already commercialized.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 0 2007

Toshiba America Medical System, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K073259
Trade/Device Name: XIDF-100A/B1, Image Processor
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications System
Regulatory Class: II
Product Code: LLZ
Dated: December 12, 2007
Received: December 13 7, 2007

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Toshiba America Medical Systems, Inc.
Pre-Market Notification 510(k) for XIDF-100A/B1 Image Processor

Indications for Use

510(k) Number (if known):

Device Name: XIDF-100A/B1, Image Processor

Indications for Use:

This device is designed to be used with Toshiba Infinix Angiography X-ray Systems and a 3D Workstation. The image processor receives 2D images and converts the data to 3D images sets that are transmitted to the 3D Workstation for viewing. The device is indicated for imaging both hard and soft tissue, as well as other internal body structures to facilitate diagnosis, surgical planning, interventional procedures and treatment follow-up.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K073259